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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

Applicant: Sterzer et al.

Appeal No.

Serial No.: 07/819,424

Serial No.: 10/822,367

Filed: April 12, 2004

Title: INFLATABLE BALLOON CATHETER STRUCTURAL DESIGNS
AND METHODS FOR TREATING DISEASED TISSUE
OF A PATIENT

Art Unit: 3739

Examiner: Rosiland Stacie Rollins

APPLICANT'S APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-14501

Sir:

This is an appeal from the Office action of January 13, 2005 finally rejecting (1) Claims 1-10 and 17 under 35 U.S.C. 102(b) as being anticipated by Kasevich et al. (US 5057106) and (2) Claims 11-16 under 35 U.S.C. 103 (a) as being unpatentable over Kasevich et al. further in view of Sterzer et al. (US 5688050) For purposes of this appeal, Claim 12 is shown as amended in the Amendment under 37 CFR 1.116 (filed February 11, 2005) to overcome the indefinite rejection thereof as indefinite under 35 U.S.C. 112, second paragraph.

Enclosed is a check for \$250.00 to cover the required fee for the filing of Applicant's Appeal Brief.

DIGEST OF APPLICANT'S INVENTION

As the title to the invention specification and the "Field of Invention" (page 1, lines 8-13) make clear, applicant's invention is directed to balloon catheter designs which incorporate an antenna cooperatively situated with respect to an external balloon surface for use in treating diseased tissue of a patient.

The respective teachings of prior-art United States patent application 10/337,159 (now US patent 6,847,848 B2) and United States patents 5,007,437, 5,992,419 and 4,190,053 (page 1, line 21 to page 2, line 18) are incorporated by reference.

FIGURE 1 (described page 3, line 25 to page 4, line 6) shows an example of a typical microwave prior-art balloon catheter design for treating diseased prostate tissue of a patient. This catheter design, in use, includes an internal antenna situated within an inflated balloon in which the antenna is separated from the exterior surface of the balloon pressing the urethral tissue proximate to the diseased prostate tissue by the balloon-inflating fluid (e.g. water).

FIGURES 2a, 2b and 2c (described on page 4, line 7 to page 5, line 19) show an experimental embodiment of applicant's invention that employs a directional spiral antenna situated on the external surface of a longitudinally-split silicone-rubber tube that surrounds the catheter balloon

FIGURES 3a, 3b, 4a, 4b, 5a and 5b (described on page 5, line 20 to page 6, line 29) show a first preferred embodiment of the present invention which, like the experimental embodiment of FIGURES 2a, 2b and 2c, also employs a directional spiral antenna situated on the external surface of a longitudinally-split silicone-rubber tube that surrounds the catheter balloon. In addition, this first preferred embodiment employs an inlet lumen to transport a coolant fluid (either a gas or preferentially a liquid, such as water having a high heat capacity) to fill and thereby inflate the catheter balloon and an outlet lumen to extract coolant fluid from the catheter balloon. For cooling purposes, the coolant fluid may be continuously pumped through the catheter balloon.

FIGURE 6 (described on page 6, line 30 to page 10, line 30) shows the use of this first preferred embodiment in the treatment of diseased prostate tissue, such as malignant tumor tissue within non-diseased prostate tissue or

Benign Prostatic Hypertrophy (BPH). The directional spiral antenna, which is situated in cooperative relationship with the exterior surface of a coolant-fluid inflated catheter balloon, is in direct and intimate contact with the utheral lining tissue overlying the non-diseased prostate tissue located closest to the diseased malignant tumor tissue. This arrangement causes the pattern of the microwave radiation transmitted from the external directional antenna and directed toward the malignant tumor tissue to be spatially confined to and effect only the desired heating of the targeted malignant tumor tissue and the undesired heating of the intervening healthy prostate tissue, as well as the lining tissue of urethra. The undesired heating of the intervening healthy prostate tissue and lining tissue of urethra is limited to a maximum safe temperature of 42°C by the continuously-flowing, high heat capacity coolant fluid (e.g. water), while a multi-frequency microwave radiometer continuously measures the temperature of the heated tissues. Further, this continuously-measured temperature by the multi-frequency microwave radiometer may be both fed back to the microwave power generator to control the power output thereof supplied to the radiating antenna and to control the amount of coolant fluid cooling. This makes it feasible to minimize the amount of microwave power needed, while maximizing the proportion of the radiation absorbed by the targeted tumor tissue and minimizing the proportion of the radiation absorbed by all of the intervening substance between the radiating antenna and the targeted tumor tissue. In the case of FIGURE 6, where external directional antenna is in direct contact with the lining tissue of urethra, the intervening substance is confined to only the lining tissue of urethra and the healthy prostate tissue. Further, by also measuring the surface temperature of the urethral lining tissue, a computer can use readings of the surface and radiometric temperatures to control both the amount of microwave heating and surface cooling in order to generate the desired optimum temperature distributions. In particular, the depth of heating is controlled by providing colder surface temperatures, which results in more power being delivered to the underlying diseased tissue (e.g., prostate malignant tumor tissue) without damaging the surface tissues. Thus, the deeper will be the depth of heating of the underlying diseased tissue. In particular, overheating of the sphincters of the urethra, with consequent damage thereto is avoided by such spatially-localized heating of targeted diseased prostate tissue (e.g. prostate cancer

lesions or BPH) to a temperature high enough to cause ablation thereof or to cause the urethral tissue lining the prostate to form a "biological stent" (disclosed in prior-art United States patent 5,992,419) in the urethra because the tissue surrounding the urethra can be safely raised to higher temperatures than is safely possible with conventional balloon catheters.

FIGURES 7a and 7b (described on page 10, line 23 to page 11, line 25) shows a second preferred embodiment of the present invention that comprises (1) a helical omnidirectional monopole antenna situated in cooperative relationship with the exterior surface of the balloon of a balloon catheter and (2) coolant-fluid inlet and outlet lumens situated within the catheter. More specifically, the antenna constitutes metallic helical spring windings enveloping the exterior longitudinal surface of the balloon in a deflated state, with the most proximate winding of the spring being attached to the inner conductor of a microwave feedline thereto. When the balloon is inflated, the spring tends to unwind under balloon pressure, thereby increasing its diameter so that it remains in proximity to the exterior surface of the balloon in its inflated state. Thereafter, when the balloon is deflated, the restoring force of the spring returns it to its neutral state. A balloon catheter incorporating an antenna having this helical omnidirectional configuration would be particularly suitable for use as an interstitial probe, for treating sub-coetaneous diseased tissue of a patient, such as (1) deep-seated tumors and (2) varicose veins, as disclosed in the aforesaid prior-art United States patent application 10/337,159.

In addition to the first and second preferred embodiments of the present invention described above, the external antenna's configuration may comprise metallic printing directly on the exterior surface of the balloon. (In the case of a spiral microstrip configuration, the metallic ground plane would be directly printed on the internal surface of the balloon.)

APPEALED CLAIMS

1. In a balloon catheter suitable for use in treating diseased tissue of a patient, wherein said balloon catheter comprises a catheter body, an inflatable balloon surrounding said catheter body, and an antenna, wherein in use (1) said catheter with said balloon in a deflated state may first be positioned so that said antenna is aligned with said patient's diseased tissue and (2) said balloon may then be inflated so that an exterior surface of said balloon presses said diseased tissue while said antenna transmits radiant energy to said diseased tissue thereby to effect the heating of said diseased tissue; the improvement wherein:

 said antenna is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing said diseased tissue to result in said antenna being in direct contact with irradiated tissue of said patient.

2. The balloon catheter defined in Claim 1, wherein said catheter body comprises:

 an input lumen that provides a first pathway for coolant fluid from a source situated outside of said balloon catheter to enter said balloon; and

 an output lumen that provides a second pathway for said to leave said balloon and exit said balloon catheter.

3. The balloon catheter defined in Claim 1, wherein:
 said external antenna is a directional antenna.

4. The balloon catheter defined in Claim 3, wherein:

 said external directional antenna comprises a spiral microstrip structure.

5. The balloon catheter defined in Claim 4, wherein said spiral microstrip structure comprises:

 longitudinally-split plastic tubing having an inner longitudinal surface thereof enveloping said longitudinal external surface of said balloon with a metallic ground plane portion of said external directional antenna directly attached to said inner longitudinal surface of said tubing and a metallic spiral portion of said external directional antenna directly attached to an outer longitudinal surface of said tubing.

6. The balloon catheter defined in Claim 1, wherein:
 said external antenna is an omnidirectional antenna.

7. The balloon catheter defined in Claim 6, wherein:

 said external omnidirectional antenna comprises a metallic helical structure surrounding said longitudinal external surface of said balloon.

8. The balloon catheter defined in Claim 1, wherein:

 said external antenna is an external microwave antenna for transmitting microwave radiant energy to said diseased tissue while said balloon is inflated thereby to effect the heating of said diseased tissue.

9. In a system suitable for use in heat treating diseased prostate tissue of a patient, wherein said system comprises a balloon catheter including a catheter body, an inflatable balloon surrounding said catheter body, and an antenna; wherein in use (1) said catheter with said balloon in a deflated state may first be inserted into an orifice of said patient and positioned so that said antenna is aligned with said patient's prostate tissue and (2) said balloon may then be inflated so that an exterior surface of said balloon presses against lining tissue of said orifice that is adjacent to said patient's prostate tissue, the improvement wherein:

 said antenna is a directional antenna that (1) is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing against said lining tissue of said orifice that is adjacent to said patient's prostate tissue, to result in said antenna being in direct contact with said lining tissue of said patient and (2) transmits radiant energy of a given frequency band to said diseased prostate tissue in response to power within said given frequency band being supplied to said antenna; and

 a power source and means including a feedline for supplying a given amount of power within said given frequency band to said external directional antenna, thereby to irradiate said diseased tissue and thereby effect the heating to a given therapeutic temperature.

10. The system defined in Claim 9, wherein:

 said given frequency band is the 915 MHz frequency band.

11. The system defined in Claim 9, wherein said system further comprises a radiometer, and wherein:

 said means including a feedline further includes a single-pole two-position switch for forwarding said given amount of power within said given frequency band from said power source to said feedline when said single-pole two-position switch is in a first switch position thereof and for forwarding thermal radiation received by said external directional antenna and supplied to said feedline to said radiometer when said single-pole two-position switch is in a second switch position thereof;

 whereby said radiometer provides a reading indicative of the temperature of said irradiated diseased tissue.

12. The system defined in Claim 11, wherein:

 said means including a feedline further includes means for switching said single-pole two-position switch back and forth between its first and second switch positions thereby to continuously provide from said radiometer a reading of said irradiated diseased tissue's current temperature.

13. The system defined in Claim 12, wherein said balloon catheter comprises:

means for supplying said balloon's interior volume with a coolant fluid for removing heat from said lining tissue of said orifice thereby to maintain the temperature of said lining tissue of said orifice at a safe temperature.

14. The system defined in Claim 13, wherein:

said safe temperature is no higher than 42°C.

15. The system defined in Claim 13, wherein said balloon catheter comprises a catheter body surrounded by said balloon thereof, and said means for supplying said balloon's interior volume with a coolant fluid comprises:

an input lumen in said catheter body that provides a first pathway for coolant fluid from a source situated outside of said balloon catheter to enter said balloon; and

an output lumen in said catheter body that provides a second pathway for said to leave said balloon and exit said balloon catheter.

16. The system defined in Claim 15, wherein said orifice of said patient is said patient's urethra.

17. The system defined in Claim 9, wherein said orifice of said patient is said patient's urethra.

DIGEST OF CITED PRIOR ART

Kasevich et al, (US 5057106)

The title of Kasevich et al, is "Microwave Balloon Angioplasty." The "Field of Invention" paragraph of the Kasevich et al, specification (Column 1, lines 14-21) includes the sentence "The present invention relates in general to microwave balloon angioplasty, and pertains more particularly to a microwave or radiofrequency catheter system for the heating of plaque in arteries or blood vessels." (Column 1, lines 14-17). Each of Claims 1-37 of Kasevich et al, is directed to "A microwave catheter system for heating arterial plaque", while Claim 38 is directed to "A device for heating arterial plaque."

Prior to providing a Detailed Description of any of their FIGURES, Column 5, lines 27-37 of the Kasevich et al. specification includes the following paragraph:

"In accordance with the present invention, there are now described a number of techniques for providing control of the quantity of microwave energy that is coupled to coronary vessel plaque without heating vessel tissue. A collinear array is provided inside the balloon or between two balloon surfaces (balloon inside a balloon). In accordance with one embodiment of the invention, a printed microstrip circuit radiator or antenna pattern is configured in one of several ways, such as inside the balloon, between the balloon surfaces or outside the balloon. *In accordance with one embodiment of the invention, a printed microstrip circuit radiator or antenna pattern is configured in one of several ways, such as inside the balloon, between the balloon surfaces or outside the balloon* (underlining and italics added)."

FIGURES 1, 3, 6 and 13 of Kasevich et al. show different configurations of an antenna situated inside the balloon and FIGURES 4 and 5 of Kasevich et al. show different configurations of an antenna situated between the balloon surfaces, but only FIGURES 11 and 14 of Kasevich et al. comprise antenna structures that extend outside of the balloon. In the case of FIGURE 11 (described on Column 9, lines 22-49), the antenna structure comprises (1) a guide wire passing through the entire length of the balloon

and terminating in tip 92 situated outside the distal end of the balloon and (2) chokes A and B situated within the balloon, respectively, in the vicinity of the proximate and distal ends of thereof. This results in only the portion of the guide wire between chokes A and B inside the balloon operating as a radiator. Therefore, tip 92 of FIGURE 11 cannot be considered a radiator situated outside of the balloon. However, FIGURE 14 (described on Column 6, lines 3-16), which comprises an antenna extending through the length of the balloon and terminating in a tip situated outside of the distal end of the balloon which has a ferrite layer thereon which is heated by microwave energy in the antenna, The heated ferrite at the antenna tip, with the balloon in a deflated state, may be used to melt, ablate and remove some plaque from a fully-blocked artery. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out.

Sterzer et al., (US 5688050)

Sterzer et al. is directed to a differential radiometer system suitable for use in medical diagnostics (Column 9. Lines 33-35), not medical treatment, in making differential subsurface body tissue temperature measurements when inserted into natural openings of the body. More specifically, a differential radiometer applicator (shown in FIGURE 5b and described on Column 9, lines 33-46), which includes two closely-spaced antennas within a catheter, is connected to a differential radiometer structure (shown in FIGURES 5 and 5a and described on Column 8, line 44 to Column 9, line 432) that incorporates a single-pole two-position switch. FIGURE 5c (described on Column 9, lines 47-67) explains the manner of using this differential radiometer system with the applicator slowly inserted into the urethra of a patient to thereby be able to detect cancerous prostate lesions in accordance the obtained temperature profile.

HISTORY OF THE PROSECUTION

1. Filing of Application, dated 04-12-04: Application includes 17 original claims, with the novelty portion of original Claim 1 (written in Jepson form) stating broadly, "said antenna is an external antenna that is situated outside of said balloon in cooperative relationship with a longitudinal external surface of said balloon."
2. First Office action, dated 07-23-04:
(1) Claims 1-10 and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by Kasevich et al. (US 5057106) based on FIGURE 4 and Column 5, line 37 of the Kasevich et al. disclosure and (2) Claims 11-16 were rejected under 35 U.S.C. 103 as being unpatentable over Kasevich et al. further in view of the radiometer teaching of Sterser et al. (US 5688050). In addition, Claims 9-17 were rejected under 35 U.S.C. 101 as directed to non-statutory subject matter and Claims 12-16 were rejected under 35 U.S.C. 112, second paragraph as indefinite for failing to provide a structural limitation within an apparatus claim.
3. Filing of Amendment, dated 10-01-04:
The scope of the novelty portion of independent Claim 1 (written in Jepson form) was narrowed by this amendment to now state, "said antenna is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing said diseased tissue to result in said antenna being in direct contact with irradiated tissue of said patient." Independent Claim 9 1 (also written in Jepson form), which is directed to the treatment of prostate diseased tissue, was amended both to overcome the rejection thereof under 35 U.S.C. 101 and to narrow the scope of the novelty portion thereof in a manner similar to that of independent Claim 1. The Remarks of this Amendment (1) set forth applicant's reasons for the allowability of amended independent Claim 1 over the teaching of the Kasevich et al. disclosure and (2) urged the allowance of the remaining Claims 2-17 for at least the same reasons as amended independent Claim 1.

4. Second Office action, dated 01-13-05:

(1) Amended independent Claims 1 and 9 (together with their dependent Claims 2-10 and 17) were finally rejected under 35 U.S.C. 102(b) as being anticipated by Kasevich et al. (US 5057106) again based on FIGURE 4 and Column 5, lines 35-37 of the Kasevich et al. disclosure and (2) Claims 11-16 were finally rejected under 35 U.S.C. 103 as being unpatentable over Kasevich et al. further in view of the radiometer teaching of Sterser et al. (US 5688050). Further, Claims 12-16 were finally rejected under 35 U.S.C. 112, second paragraph as indefinite for failing to provide a structural limitation within an apparatus claim.

5. Telephone interviews with Examiner, dated 01-25-05 and 01-31-05:

Applicant, in the first interview, pointed out to the Examiner that the antenna shown in FIGURE 4 of Kasevich et al. is “embedded in balloon skin” (as stated in FIGURE 4). Therefore, neither the antenna shown in FIGURE 4 nor, for that matter, any of the antenna configurations shown in other figures of Kasevich et al., show an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in said antenna being in direct contact with irradiated tissue of the patient, as called for in amended independent Claim 1. The Examiner, in the second interview, agreed that none of the figures of Kasevich et al. of show the antenna configuration defined for in amended independent Claim 1. However, it was the Examiner’s position that the sentence set forth on Column 1, lines 33-37 of Kasevich et al., which states on line 37 that the antenna can be configured to be “outside the balloon”, is sufficient to anticipate the specific antenna structure defined in amended Claim 1.

6. Amendment under 37 CFR 1.116, dated 2-11-05:

Claim 12 was amended to overcome the final rejection of Claims 12-16 under 35 U.S.C. 112, second paragraph by providing the required structural limitation within Claim 12 apparatus claim. In addition, the Remarks of the Amendment under 37 CFR 1.116 presented Applicant’s

reasons why the teaching of Kasevich et al., in general, and their statement, in particular, that their antenna can be configured to be "outside the balloon", fails to anticipate the antenna configuration specifically defined in applicant's amended independent Claim 1.

7. Advisory action, dated 3-16-05:

The Examiner finds that the Amendment under 37 CFR 1.116 fails to place the application in condition for allowance.

8. Notice of Appeal, dated 04-11-05:

Appealed are the final rejection of (1) amended independent Claims 1 and 9 (together with their dependent Claims 2-10 and 17 under 35 U.S.C. 102(b) as being anticipated by Kasevich et al. (US 5057106) and (2) Claims 11-16 under 35 U.S.C. 103 as being unpatentable over Kasevich et al. further in view of the radiometer teaching of Sterser et al. (US 5688050).

THE ISSUE AND APPLICANT'S ARGUMENT

1. The Issue:

The broad issue is whether or not Kasevich et al. shows, teaches or even suggests an inflatable balloon catheter design for treating diseased tissue of a patient, such as the design defined in amended Claim 1, which incorporates an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient. The narrow issue is whether or not the disclosure in Kasevich et al. of an antenna configuration "outside the balloon" (Column 5, line 37) anticipates the inflatable balloon catheter design defined in amended Claim 1.

2. Applicant's Argument:

It is applicant's position that (1) the intended uses of the inflatable balloon catheter designs taught, respectively, by applicant and by Kasevich et al. are entirely different from one another and (2) because of this difference in intended use, Kasevich et al. intentionally avoids the teaching of an inflatable balloon catheter design for treating diseased tissue of a patient, which incorporates an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient, as called for in amended Claim 1.

The disclosed intended use of applicant's antenna situated in cooperative relationship with the exterior surface of the balloon is to heat the diseased tissue of a patient with absorbed radiant energy to a temperature high enough to cause necrosis of the diseased tissue, while still maintaining the neighboring non-diseased tissue of the patient at a safe temperature. This results from the fact that a such-situated antenna on an inflated balloon pressing the diseased tissue results in concentrating a very large proportion of a relatively large amount of transmitted radiant energy from the antenna in the diseased tissue, thereby limiting the amount of transmitted radiant energy from the antenna in the non-diseased tissue to a very small proportion. Examples of necrosis of the diseased tissue, while maintaining

the neighboring non-diseased tissue at a safe temperature, disclosed by applicant are (1) destruction of malignant prostate tumor tissue (FIGURE 6 and Page 6, line 30 to Page 9, line 9), (2) producing “biological stents” (Page 9, lines 16-31), (3) ablating cancerous and BPH prostate tissue (Page 9, line 32 to Page 10, line 15), and (4) treating sub-cutaneous diseased tissue, such as deep-seated tumors and varicose veins (page 11, lines 21-25).

The disclosed intended use of all but one of the various antenna configurations of Kasevich et al., in the treatment of coronary vessel plaque with microwave balloon angioplasty is “to deliver microwave energy to a specific layer of plaque without heating wall tissue during pressure application by the balloon” (Column 5, lines 15-17) and “control of the quantity of microwave energy that is coupled to coronary vessel plaque without heating vessel tissue” (Column 5, lines 29-31). Note that these lines 29-31 appear in the same paragraph Column 5, lines 27-37 in which the several antenna configurations are stated to include an antenna configuration “outside the balloon” (Column 5, line 37), relied on by the Examiner in finally rejecting amended Claim 1 under 35 U.S.C. 102(b) as being anticipated by Kasevich et al.

The only one of the various antenna configurations of Kasevich et al. that includes an antenna configuration “outside the balloon” is shown in their FIGURE 14 (the structure of which may be modified as shown in FIGURE 27). Kasevich et al. state, “FIG. 14 shows the antenna A extending through the balloon B and having at its tip T a concentric layer of ferrite material that may have a Curie temperature in the 400°C-500°C range. Microwave energy is rapidly absorbed in the ferrite when this material is at a current maximum of the antenna. The primary function of this hot tip (when the ferrite is at the far end of the antenna) is to melt plaque (ablation). This is used for those cases where the artery is fully blocked by plaque, and it would therefore be necessary to remove some plaque in order to insert the balloon. In FIG. 14, note the plaque volume at V. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out.” (Column 6, lines 3-16). Kasevich et al. further state, “As indicated previously, FIG. 27 herein teaches the use of a lossy sleeve 80 for focused heating. An alternate embodiment is to employ two ferrite sleeves F1 and F2, as illustrated in FIG. 14, some distance apart along the antenna axis but outside of and essentially in front of the balloon. In this regard, the arrow A1 in FIG. 14 illustrates the

direction of the insertion of the antenna structure." (Column 6, lines 17-23).). Kasevich et al. still further state, "As indicated previously, FIG. 14 shows a two-ferrite geometry. The ferrites F1 and F2 hear through the plaque (occluded artery) using microwave frequency F1. To withdraw the antenna back through the plaque and avoid sticking, the ferrite F2 is tuned to a frequency F2. It remains hot to allow the antenna to be withdrawn prior to inserting the balloon and using the antenna in its normal plaque welding mode. Also, ferrite, hot tip antenna may be completely removed from the catheter in a different antenna design employed for low temperature operation." (Column 6, lines 24-34).

It is plain from the above-quoted statements of Kasevich et al. that the "outside the balloon" antenna configuration, shown in FIGURE 14 of Kasevich et al., does not structurally or functionally show, or even suggest, an inflatable balloon catheter design for treating diseased tissue of a patient, which incorporates an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient, as called for in amended Claim 1.

Both applicant's antenna configuration, which is situated in cooperative relationship with the exterior surface of the balloon, and the FIGURE 4 antenna configuration of Kasevich et al., in which the antenna is embedded in the skin of the balloon, share the microwave-efficiency advantage over those antenna configurations in which the antenna is situated inside of the balloon by not wasting radiated microwave energy in heating the coolant fluid inflating the balloon. However, the structural complexity of the FIGURE 4 skin-embedded antenna configuration of Kasevich et al. is significantly greater than that of applicant's simple configuration of merely situating the antenna in cooperative relationship with the exterior surface of the balloon. The question arises as to why Kasevich et al. chose this more complex antenna configuration. It is believed that the reason for their choice was to avoid unwanted heating of vessel wall tissue. (See Column 5, lines 15-17 and lines 27-31, discussed above). Therefore, the failure of Kasevich et al. to show or teach the configuration of situating the antenna in cooperative relationship with the exterior surface of the balloon was not an oversight on their part, but was deliberate.

CONCLUSION

For all the reasons set forth above in Applicant's Argument, the Board of Patent Appeals and Interferences is respectfully urged to reverse the final rejection by the Examiner of (1) amended independent Claim 1, together with dependent Claims 1-8, amended independent Claim 9, dependent Claims 10 and dependent Claim 17 under 35 U.S.C. 102(b) as anticipated by Kasevich et al. (US 5057106) and (2) dependent Claim 11, amended dependent Claim 12 and dependent Claims 13-16 under 35 U.S.C. 103(a) as unpatentable over the primary reference Kasevich et al. further in view of Sterzer et al. (US 5688050), and allow each of these Claims 1-17.

Respectfully submitted,

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